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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte RODERICK JOHN SCOTT

Appeal 2008-004077
Application 10/058,825
Technology Center 1600

Decided: January 6, 2010

Before JAMES T. MOORE, *Vice Chief Administrative Patent Judge*, and DEMETRA J. MILLS, ERIC GRIMES, RICHARD M. LEBOVITZ, and FRANCISCO C. PRATS, *Administrative Patent Judges*.

Opinion for the Board filed by *Administrative Patent Judge* GRIMES.

Opinion Dissenting filed by *Administrative Patent Judge* MILLS, joined by *Administrative Patent Judge* PRATS.

DECISION ON REQUEST FOR REHEARING

Appellant has requested rehearing of the decision entered June 2, 2009 ("Decision"), which affirmed the Examiner's rejections for

nonenablement and lack of adequate written description. The Request for Rehearing is granted.

DISCUSSION

The Examiner rejected all of the pending claims as indefinite, nonenabled, and lacking adequate written description (Ans. 3, 4-5, and 7). The Decision reversed the rejection for indefiniteness (Decision 12) but affirmed the rejection of all of the claims for lack of adequate written description¹ and affirmed the rejection of claims 20, 21, 62-67, 69, 71, 76-78, 80-82, 85-90, and 93 for nonenablement (*id.* at 42, 47).

1. Enablement

Issues

Appellant contends that the Decision's reliance on evidence of unpredictability as to the effect of decreased methylation on different parts of a plant, supporting a conclusion of nonenablement, amounted to a new ground of rejection under 37 C.F.R. § 41.50(b) (Req. Reh'*g.* 9). In response to the assertedly new ground of rejection, Appellant argues that the references relied on in the Decision "disclose only the use of the CaMV 35S constitutive promoter or vegetative tissue specific promoter. . . . In contrast, the claimed invention targets expression of the Met1 construct (or *Z. mays*

¹ Although the Decision stated at one point that the written description rejection was affirmed for "all claims (except claims 83, 84, 91, and 92)" (Decision 47), that statement was an obvious error since the Decision had already addressed the separate argument of claims 83, 84, 91, and 92 and stated that "the written description rejection of claims 83, 84, 91, and 92 is affirmed" (Decision 47).

Met1 ortholog construct) to the female germ line.” (*Id.*). Appellant argues that those skilled in the art would have understood that limiting expression to the female germ line, as claimed, would avoid any unpredictability resulting from generalized expression that is shown in the cited references (*id.* at 9-10).

The issues with respect to this rejection are:

- (1) Did the Decision change the basic thrust of the rejection so as to make, in effect, a new ground of rejection for nonenablement? and
- (2) If so, has Appellant shown that the evidence of record does not support the basis for the enablement rejection set out in the Decision?

Findings of Fact

1. The statement of the rejection in the Examiner’s Answer reads as follows:

[T]he specification . . . does not reasonably provide enablement for claims broadly drawn to a method of modifying the endosperm from any plant comprising down-regulating any DNA methylating enzyme using a sequence whose transcription product comprises a partial or full length *Arabidopsis* Met1 sequence or which comprises a partial or full-length *Zea mays* sequence orthologous to the *Arabidopsis* Met1 sequence, or wherein the nucleic acid is a partial or full length sequence in sense or antisense orientation.

(Ans. 7.)

2. The Examiner found that the “state-of-the-art teaches down-regulating methylating genes produces unpredictable results. Jacobsen et al (2000, *Current Biology* 10:179-186)” (*id.* at 9).
3. The Examiner found that a “partial sequence”

read[s] on a great number of sequences because a partial sequence reads on any two nucleotides from Appellant's Met1 sequence. . . . Appellant has not taught which regions of the respective polynucleotides can be used to amplify, for example, the *Zea mays* orthologous sequence, or which regions can be used as a probe to isolate any of said polynucleotide sequences whose transcription product comprises a partial *Arabidopsis* or *Zea mays* Met1 sequence that is effective for downregulating one or more DNA methylating enzymes.

(*Id.* at 9-10.)

4. The Examiner found that “[u]sing DNA sequences to reduce expression of the endogenous corresponding gene through the mechanism of sense suppression produces unpredictable results. Gutterson (1995, HortScience 30(5):964-966)” (*id.* at 10).

5. The Examiner found that the “state-of-the-art teaches that antisense molecules that exhibit less than 100% sequence identity to the target sequence produce unexpected results. Emery et al (2003, Current Biology 13:1768-1774)” (*id.*).

6. The Examiner concluded:

In the absence of guidance, undue trial and error experimentation would be required for one of ordinary skill in the art to screen through the multitude of non-exemplified sequences, either by using non-disclosed fragments of a nucleic acid encoding the *Arabidopsis* Met1 protein as probes or by designing primers to undisclosed regions of a nucleic acid encoding the *Arabidopsis* Met1 protein and isolating or amplifying fragments, subcloning the fragments, producing expression vectors and transforming plants therewith, in order to identify those, if any, that when over-expressed in female germ line cells down-regulate one or more DNA methylating enzymes present in the plant and produce a plant whose seeds produce a modified endosperm.

(*Id.* at 11.)

7. The Decision found that several references provide evidence of unpredictability in the art (Decision 20 (citing Hibino and Bolitho), 21 (citing Salehuzzaman and Elkind)).

8. The Decision concluded that Hibino, Bolitho, Salehuzzaman, and Elkind do not “support that a resulting decrease in overall methylation in any plant would predictably result in production of a modified endosperm” (Decision 35-36).

9. The Decision reached the same conclusion with respect to Cannon, Emery, and Gutterson (*id.* at 31, 36, 37); the known sequences of the corn, carrot, pea, and tomato Met1 genes (*id.* at 38); and the Oliver, van der Krol, Carron, and Einset abstracts (*id.* at 39).

10. The Decision concluded that

a preponderance of the evidence before us supports the finding that the state of the art is unpredictable and that more disclosure is required to enable and support the down regulation of Met1 in any plant to produce a modified endosperm.... In particular, we find that the evidence before us shows that down regulation of plant genes often has an effect on one portion of a plant and not other portions of a plant. Down regulation of a plant gene may affect a tuber, root, flower, or endosperm in an unpredictable manner.

(*Id.* at 41.)

11. The Decision did not address the experimentation required to practice the claimed method using partial sequences of the *Arabidopsis* or *Zea mays* Met1 gene.

12. Hibino discloses introducing an antisense gene for *Aralia cordata* cinnamyl alcohol dehydrogenase into tobacco plants (Hibino 929, left col.)

under the control of “a strong plant promoter, the 35S CaMV promoter” (*id.* at 929, right col.).

13. Bolitho discloses introducing an antisense gene for apple 1-aminocyclopropane-1-carboxylic acid oxidase into tomato plants (Bolitho 91) under the control of “the cauliflower mosaic virus 35 S promoter” (*id.* at 93, left col.).

14. Salehuzzaman discloses introducing an antisense gene for cassava granule-bound starch synthase (GBSS) into potato plants under the control of the potato GBSS promoter (Salehuzzaman, abstract); GBSS is expressed “in a number of different organs, but most abundantly in tubers” (*id.*).

15. Elkind discloses “introduction of a heterologous (bean) phenylalanine ammonia-lyase . . . gene, modified by inclusion of cauliflower mosaic virus 35S enhancer sequences in its promoter,” into tobacco plants (Elkind, abstract).

16. The Specification discloses that “*Arabidopsis* plants expressing a DNA methyltransferase 1 (Met1) antisense (Met1as) gene contain reduced levels of DNA methyltransferase activity and a correspondingly reduced level of general DNA methylation (Finnegan et al., 1995; Ronemus et al., 1996)” (Spec. 10: 27-29).

17. The Specification discloses that “*Arabidopsis* plants expressing a Met1as gene develop various developmental abnormalities at high frequency . . . including floral abnormalities (Finnegan et al., 1996)” (*id.* at 10: 30 to 11: 2).

18. The Specification discloses that the “restriction of imprint removal or attenuation to one or other sex of gamete is desirable . . . [t]o

prevent developmental abnormalities that are associated with generalised hypomethylation, such as occurs with the CaMV35S driven Met1 antisense gene" (*id.* at 15: 12-20).

19. The Specification discloses that promoters suitable for female germ line-specific expression include "promoter fragments from the *Arabidopsis AGL5* gene, the *Petunia FBP7* and *FBP11* genes, *Arabidopsis BEL1* gene, *Arabidopsis MEDEA (FIS1)* gene, *Arabidopsis FIS 2, FIE (FIS 3)*, [and] orthologs/homologues of these genes from other species" (*id.* at 16: 17-23, reference citations omitted).

20. The Specification discloses that "demethylation is approximately constitutive" in "35SMet1as female lines," which may result in reduced fitness (*id.* at 29: 12-13). The Specification discloses that "to reduce and eliminate this effect and to allow seed size changes to be obtained in a single plant it is necessary to restrict demethylation as much as possible to the germ line" (*id.* at 29: 13-15).

21. The Specification provides a working example describing the cloning of the *Arabidopsis* Met1 antisense gene under the control of the female germ line-specific AGL5 promoter (*id.* at 30: 12 to 31: 2).

22. The Specification discloses that transgenic *Arabidopsis* plants expressing the Met1 antisense/AGL5 construct "were vegetatively normal and produced flowers with the normal complement of floral organs" (*id.* at 31: 16-17).

23. The Specification discloses that transgenic *Arabidopsis* plants expressing the Met1 antisense/AGL5 construct produced seeds with a mean

weight of “40 µg, compared with a mean of 22 µg for 2x-2x seed [the control diploid plant cross]” (*id.* at 31: 26-27).

24. The Specification discloses that a Met1 antisense gene under the control of the AGL5 promoter was transformed into *Brassica campestris* and *Brassica oleraceae*, and states that the transgenic plants yielded plump, viable seeds (*id.* at 33: 16-18).

25. Claims 20 and 62 are the only independent claims pending.

26. Claim 20 reads:

20. A method for the production of modified endosperm, which comprises the step of introducing a nucleic acid molecule into a plant, the nucleic acid molecule comprising a promoter that targets expression to female germ line cells and a sequence whose transcription product comprises a partial or full-length *Arabidopsis* DNA methyltransferase 1 (Met1) sequence, wherein the introduced nucleic acid is effective for down-regulating one or more DNA methylating enzymes present in the plant, whereby the degree of DNA methylation of nucleic acid in the plant is reduced as compared to a control plant.

27. Claim 62 reads:

62. A method for the production of modified endosperm, which comprises the step of introducing a nucleic acid molecule into a plant, the nucleic acid molecule comprising a promoter that targets expression to female germ line cells and a sequence whose transcription product comprises a partial or full-length *Z. mays* DNA sequence orthologous to the *Arabidopsis* DNA methyltransferase 1 (Met1) sequence, wherein the introduced nucleic acid is effective for down-regulating one or more DNA methylating enzymes present in the plant, whereby the degree of DNA methylation of nucleic acid in the plant is reduced as compared to a control plant.

28. The sequences of the *Arabidopsis* Met1 gene and its *Zea mays* ortholog were known in the art at the time the present application was filed (Decision 22 (FF 42)).

Principles of Law

“[T]he ultimate criterion of whether a rejection is considered ‘new’ in a decision by the board is whether appellants have had fair opportunity to react to the thrust of the rejection.” *In re Kronig*, 539 F.2d 1300, 1302 (CCPA 1976).

“When rejecting a claim under the enablement requirement of section 112, the PTO bears an initial burden of setting forth a reasonable explanation as to why it believes that the scope of protection provided by that claim is not adequately enabled by the description of the invention provided in the specification of the application.” *In re Wright*, 999 F.2d 1557, 1561-62 (Fed. Cir. 1993).

“Although the statute does not say so, enablement requires that the specification teach those in the art to make and use the invention without ‘undue experimentation.’ *In re Wands*, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988). That *some* experimentation may be required is not fatal; the issue is whether the amount of experimentation required is ‘undue.’” *In re Vaeck*, 947 F.2d 488, 495 (Fed. Cir. 1991) (emphasis in original).

Analysis

The Examiner’s statement that the Specification was not enabling for “claims broadly drawn to a method of modifying the endosperm from any plant comprising down-regulating any DNA methylating enzyme” might have suggested that part of the basis for the holding of nonenablement was that the effect of down-regulating methyltransferase expression was unpredictable. But the only evidence that the Examiner relied on that would

support that view was his passing reference to Jacobsen, and the Examiner did not state that the claimed method would have been expected to produce different effects on different tissues. The Examiner's conclusion of the nonenablement rejection – the explanation of what experimentation would have been required to practice the claimed method – focused solely on determining which fragments of the Met1 gene would effectively inhibit methylation in plant cells.

By contrast, the evidentiary focus in the Decision was on whether decreasing methylation in plants predictably results in modified endosperm. The conclusion in the Decision – the explanation of why practicing the claimed method would have required undue experimentation – focused solely on evidence that inhibiting methylation produces unpredictable effects on different parts of the affected plants.

We agree with Appellant that the reasoning in the Decision changed the basic thrust of the rejection and that, therefore, Appellant is entitled to advance new arguments in the Request for Rehearing to respond to the modified rejection.

Appellant argues that the references cited in the Decision "as evidence of the alleged unpredictability of the art are not relevant to the predictability of achieving Met1 transgene expression when that expression is targeted to reproductive tissues, as presently claimed" (Req. Reh'g. 9). Appellant argues that the references cited in the Decision all showed expression under the control of the constitutive CaMV 35S promoter or a tuber-specific promoter (*id.*), and that the claimed method restricts expression of the Met1

antisense gene to the female germ line precisely to avoid such effects (*id.* at 9-10).

We agree with Appellant that the evidence relied on in the Decision does not support a conclusion that the claimed method, which uses a promoter that targets female germ line cells, would be expected to produce unpredictable effects on different parts of plants expressing a Met1 antisense gene.

Hibino, Bolitho, and Elkind disclose experiments in which an antisense gene was expressed under the control of the CaMV 35S promoter (FFs 12, 13, 15). The evidence of record shows that the CaMV 35S promoter is a “strong promoter” (FF 12) and that expression of Met1 antisense under control of the CaMV 35S promoter results in “approximately constitutive” demethylation (FF 20) or generalized hypomethylation (FF 18).

The evidence also shows that plants expressing Met1 antisense under control of the CaMV 35S promoter show developmental abnormalities (FF 17) and that the Specification discloses restricting Met1 antisense expression to only one sex of gamete to avoid such abnormalities (FF 18). The evidence shows that *Arabidopsis* plants expressing the Met1 antisense gene under the control of the female germ line-specific AGL5 promoter were vegetatively normal and produced seeds with a greater mean weight than untransformed plants (FFs 22, 23), and that *Brassica campestris* and *Brassica oleraceae* plants transformed with the same construct produced plump, viable seeds (FF 24).

Hibino, Bolitho, and Elkind therefore do not support a conclusion that the claimed method would have been expected to have unpredictable effects on different parts of transgenic plants, because the evidence of record shows that an antisense gene expressed under the control of the CaMV 35S promoter has different effects on plants than the same antisense gene expressed under the control of a female germ line-specific promoter such as AGL5. Salehuzzaman, likewise, does not support the conclusion reached in the Decision because it used a promoter that directs expression most abundantly in tubers (FF 14), rather than one that directs expression specifically in female germ line cells, and no evidence has been cited to support a conclusion that expression of an antisense gene limited to tubers would have been expected to have similar effects on transgenic plants as expression limited to the female germ line.

The evidence of record also does not support the Examiner's conclusion that making and testing partial sequences of the *Arabidopsis* and *Zea mays* Met1 genes for either antisense activity or sense suppression activity would have required undue experimentation. The Specification provides working examples that describe transformation of three species of plants with a construct that expresses an *Arabidopsis* Met1 antisense gene under the control of the AGL5 promoter (FFs 21, 22). The *Arabidopsis* Met1 gene and its *Z. mays* ortholog were known in the art (FF 28).

Seemingly, the experimentation required to practice the full scope of the claims would consist of inserting fragments of the two known Met1 genes into the disclosed expression vector and transforming the resulting vectors into plant cells as described in the Specification. The Examiner has

not provided sufficient evidence to support a conclusion that the required experimentation – even if tedious, time-consuming, or repetitive – would have been undue for a person of ordinary skill in the art at the time the present application was filed.

Conclusions of Law

The Decision changed the basic thrust of the rejection so as to make, in effect, a new ground of rejection for nonenablement. Appellant has shown that the evidence of record does not support the basis for the enablement rejection set out in the Decision or in the Examiner's Answer.

2. Written Description

Issues

Appellant contends that the Decision's reliance on a purported lack of evidence that Met1 is present in endosperm, as a basis for finding that the claims were not supported by an adequate written description in the Specification, amounted to a new ground of rejection under 37 C.F.R. § 41.50(b) (Req. Reh'g. 2). In response to the assertedly new ground of rejection, Appellant argues that the evidence of record shows that Met1 is expressed in endosperm (*id.*) and that, in any case, “a modified endosperm is the product of removing or attenuating genetic imprinting via demethylation of DNA . . . [and] inhibiting the production of Met1 in the female germ line produces ovules with hypomethylated DNA” (*id.*). Appellant also argues that the Decision's reasoning conflicts with USPTO's revised Written Description Training Materials (*id.* at 3-5).

The issues with respect to this rejection are:

- (1) Did the Decision change the basic thrust of the rejection so as to make, in effect, a new ground of rejection for lack of adequate written description? and
- (2) If so, has Appellant shown that the evidence of record does not support the basis for the written description rejection set out in the Decision?

Additional Findings of Fact

29. The Examiner found that the Specification “does not identify essential regions of the *Arabidopsis* Met1 sequence, nor any partial sequences thereof, nor any partial sequence of the *Zea mays* orthologue of the *Arabidopsis* Met1 sequence, that can be used to down-regulate one or more methylating enzymes present in a plant” (Ans. 5).

30. The Examiner found that the Specification “fails to describe a representative number of sequences whose transcription product is a partial sequence of the *Arabidopsis* Met1 sequence, or partial sequences of the *Zea mays* homologue of the *Arabidopsis* Met1 sequence, that can be used to down-regulate one or more methylating enzymes in any plant” (*id.* at 6).

31. The Examiner found that the Specification “fails to describe structural features common to members of the claimed genus of polynucleotides” (*id.*).

32. The Examiner found that “[s]ince the genus of said sequences has not been described by specific structural features, the specification fails to provide an adequate written description to support the breath [sic] of the claims” (*id.*).

33. The Decision framed the written description issue as follows: “Does the evidence . . . demonstrate that one of ordinary skill would understand that Appellant has describe[d] the invention in the full scope claimed, that is production of a modified endosperm in any plant[?]” (Decision 43).

34. The Decision found that “Appellant has failed to provide evidence that one of ordinary skill in the art was aware that Met1 is present in the endosperm of any plant type or that a full or partial antisense sequence to Met1 would result in a modified endosperm” (*id.* at 46).

35. The Decision found that “given the disclosure of a single species of *Arabidopsis* Met1 sequence, shown only to be capable of modifying endosperm production in one plant species, we agree with the Examiner that the disclosure as filed does not adequately demonstrate possession of the claimed genus encompassing all partial sequences that act to modify the endosperm of any plant” (*id.*).

36. Finnegan (1998)² discloses that “[m]ost of the known plant methyltransferase transcripts are expressed ubiquitously in vegetative and reproductive tissues. . . . METI transcripts are at least 10,000-fold more abundant than those of METII.” (Finnegan (1998) 230).

37. The Specification discloses a method for the production of modified endosperm, which comprises the step of transforming a plant . . . with a nucleic acid molecule comprising one or more regulatory sequences

² E. J. Finnegan et al., *DNA METHYLATION IN PLANTS*, 49 Ann. Rev. Plant Physiol. Plant Mol. Biol. 223-247 (1998), which was included in the Evidence Appendix attached to the Appeal Brief.

capable of directing expression in the . . . female germ line and/or gametes of the resultant plant, and one or more sequences whose expression or transcription product(s) is/are capable of altering the degree of methylation of nucleic acid.

(Spec. 15: 5-10.)

38. The Specification discloses that “the transgene can incorporate sequences which cause down regulation of methylating enzymes already present in the plant. For instance, one can use antisense sequences, e.g. the Met1as ‘gene’. In addition, it has been found that incorporation of whole or partial copies of an already present gene can result in suppression of gene expression.” (*Id.* at 18: 26-30.)

39. The Specification discloses that the “pAGL5Met1as gene [sic, vector?] could be transformed into other crop species such as . . . *Zea mays*, leading to an increase in seed size and seed quality in the transgenic plants. In this case it is most preferable to use MET1 and AGL5 orthologous sequences from . . . *Zea mays*” (*id.* at 32: 6-8).

40. On January 5, 2001, the USPTO published Guidelines for the Examination of Patent Applications under 35 U.S.C. § 112, first paragraph, Written Description Requirement. 66 Fed. Reg. 1099 (2001).

41. The Written Description Guidelines do not have the force and effect of law but reflect “the Office’s current understanding of the law” (*id.* at 1104).

42. The Appeal Brief in this application was filed June 5, 2007, and the Reply Brief was filed November 11, 2007.

43. On March 25, 2008, the USPTO revised its Training Materials applying the Written Description Guidelines. The Training Materials are accessible at www.uspto.gov/web/menu/written.pdf.

44. The Written Description Training Materials include Example 12, in which the “specification discloses a messenger RNA (mRNA) sequence that encodes newly discovered growth factor (NDG): SEQ ID NO: 1. The specification states that the invention includes antisense oligonucleotides that inhibit the production of NDG, but does not disclose the sequences of any antisense oligonucleotides.” (Written Description Training Materials 43.) The claim recites “[a]n antisense oligonucleotide complementary to all or a portion of a messenger RNA having SEQ ID NO: 1 and encoding NDG, wherein said antisense oligonucleotide inhibits the production of NDG” (*id.*).

45. Example 12 states that “the structure of all possible antisense oligonucleotides that are complementary to NDG mRNA can be predicted from the full-length complement of SEQ ID NO: 1” (*id.*), that “there are certain art-recognized correlations between the antisense oligonucleotide’s function and the structure of the target mRNA that would aid the selection of those fragments having antisense activity” (*id.* at 44), and that “[s]everal mRNA computer modeling software packages exist that . . . can be used to predict those oligonucleotides having antisense activity” (*id.*).

46. Example 12 concludes that “those of ordinary skill in the art would consider the applicant to have been in possession of the entire breadth of the claimed genus of antisense oligonucleotides based on the single species . . . of SEQ ID NO: 1” (*id.*).

Principles of Law

The Examiner “‘bears the initial burden . . . of presenting a *prima facie* case of unpatentability.’ *In re Oetiker*, 977 F.2d 1443, 1445, 24

USPQ2d 1443, 1444 (Fed. Cir. 1992). Insofar as the written description requirement is concerned, that burden is discharged by ‘presenting evidence or reasons why persons skilled in the art would not recognize in the disclosure a description of the invention defined by the claims.’” *In re Alton*, 76 F.3d 1168, 1175 (Fed. Cir. 1996).

[T]he written description requirement can be met by “show[ing] that an invention is complete by disclosure of sufficiently detailed, relevant identifying characteristics . . . i.e., complete or partial structure, other physical and/or chemical properties, functional characteristics when coupled with a known or disclosed correlation between function and structure, or some combination of such characteristics.”

Enzo Biochem, Inc. v. Gen-Probe Inc., 323 F.3d 956, 964 (Fed. Cir. 2002) (emphasis omitted).

“[T]here is no *per se* rule that an adequate written description of an invention that involves a biological macromolecule must contain a recitation of known structure.” *Falkner v. Inglis*, 448 F.3d 1357, 1366 (Fed. Cir. 2006).

“Arguments not raised in the briefs before the Board . . . are not permitted in the request for rehearing except as permitted by paragraphs (a)(2) and (a)(3) of this section.” 37 C.F.R. § 41.52(a)(1). “Upon a showing of good cause, appellant may present a new argument based upon a recent relevant decision of either the Board or a Federal Court.” 37 C.F.R. § 41.52(a)(2).

Analysis

The Examiner’s rejection was based on his finding that the Specification did not adequately describe partial sequences of the

Arabidopsis and *Zea mays* Met1 genes that would function to downregulate a methylating enzyme in a plant. The Examiner found that the Specification did not describe either a representative number of partial sequences or structural features common to members of the genus and therefore failed the test of adequate written description set out in *University of California v. Eli Lilly and Co.*, 119 F.3d 1559 (Fed. Cir. 1997). The Decision, by contrast, focused on whether the Specification provided a description of Met1 sequences that would result in modified endosperm when transformed into plants.

The issue of whether an *Arabidopsis* or *Z. mays* Met1 sequence will downregulate a methylating enzyme in a plant – the Examiner’s basis of the rejection – is different from the issue of whether a sequence that downregulates a methylating enzyme in a plant will result in modified endosperm – the Decision’s basis for affirming the rejection. We agree with Appellant that the reasoning in the Decision changed the basic thrust of the rejection and that, therefore, Appellant is entitled to advance new arguments in the Request for Rehearing to respond to the modified rejection.

Appellant argues that the evidence shows that Met1 is expressed in endosperm, and thus the reasoning relied on in the Decision does not support a finding of lack of adequate written description (Req. Reh’g. 2). We agree with Appellant’s reading of the evidence. Finnegan (1998) states that most plant methyltransferases are expressed ubiquitously in vegetative and reproductive tissues, and that Met1 is much more abundant than Met2 (FF 36). The evidence also shows that expressing a Met1 antisense transcript in female germ line cells results in heavier seeds; i.e., seeds with modified

endosperm, as claimed (FF 23). A preponderance of the evidence therefore supports a finding that Met1 is expressed in endosperm and that expression of a Met1 antisense gene in female germ line cells results in modified endosperm.

Appellant also argues that the Decision's finding that the claims are not supported by the Specification is contrary to the USPTO's revised Written Description Training Materials (Req. Reh'g. 3-5). This argument was not made in the Appeal Brief or Reply Brief, but one of the exceptions to the rule against new arguments in a Request for Rehearing is a new argument based on a recent relevant decision of the Board or a Federal court. 37 C.F.R. § 41.52(a)(2). Appellant's argument is not based on a Board or court decision, but it is based on a revision of the USPTO's application of the written description requirement that was published after briefing in this appeal had concluded. We therefore consider the new argument to fall within the exception created by 37 C.F.R. § 41.52(a)(2).

Appellant argues that the revised Training Materials "demonstrate that one of ordinary skill in the art would have considered the Appellants to have had possession of the entire genus of partial-length oligonucleotides and polynucleotides that can be predicted from the full-length sequences of *Arabidopsis* Met1 and the *Z. mays* Met1 ortholog, having any orientation or length" (Req. Reh'g. 4).

We agree with Appellant that the evidence supports a finding that the Specification adequately describes the claimed method. The Examiner rejected the claims on the basis that the Specification does not describe the partial sequences of the *Arabidopsis* and *Z. mays* Met1 genes that would

function to downregulate Met1 in a plant (FFs 29-32). As evidenced by the revised Written Description Training Materials' Example 12, however, that level of description is not required to show possession of a genus of antisense nucleic acids that are part of a longer, fully described sequence.

The Written Description Guidelines, and by extension their accompanying Training Materials, do not have the force of law but they do reflect the USPTO's usual application of the law to similar facts. To the extent that they do not conflict with the statute or binding case law, therefore, they are entitled to consideration. In this case, the Training Materials show that those of skill in the antisense art recognized certain correlations between the structure of a nucleic acid and its function as an antisense inhibitor of gene expression. The Training Materials conclude that, because of those correlations, describing a full-length antisense nucleic acid would have been recognized by those skilled in the art to show possession of other species that together are representative of the genus of antisense nucleic acids that are fragments of the full-length sequence.

We are persuaded by the Appellant's arguments on this point. The full-length sequences of the *Arabidopsis* and *Z. mays* Met1 genes were known in the art when this application was filed (FF 28). The Specification shows that introducing a full-length *Arabidopsis* Met1 antisense gene into plants causes them to produce heavier seeds; i.e., seeds with modified endosperm (FF 23). We find that the full-length *Arabidopsis* Met1 antisense gene described in the Specification, and the full-length *Z. mays* Met1 antisense gene that is the complement of the known *Z. mays* Met1 gene, would have been recognized by those skilled in the art to show possession of

the partial-length Met1 antisense sequences encompassed by the claims on appeal.

Conclusions of Law

The Decision changed the basic thrust of the rejection so as to make, in effect, a new ground of rejection for lack of adequate written description. Appellant has shown that the evidence of record does not support the basis for the written description rejection set out in the Decision.

SUMMARY

We grant the request for rehearing and reverse the rejections for nonenablement and lack of adequate written description.

REHEARING GRANTED

MILLS, *Administrative Patent Judge*, joined by Administrative Patent Judge PRATS, dissenting.

We respectfully dissent.

WRITTEN DESCRIPTION

ISSUE

Has Appellant shown that the Board presented a new ground of rejection in the Decision by changing the thrust of the Examiner's rejection? Can Appellant present new evidence in a Request for Rehearing?

FINDINGS OF FACT

1. In the Decision we found regarding the Jacobsen Declaration, that "Dr. Jacobsen does not address how to predictably alter the phenotype of the endosperm or seed in any plant or evidence that methyltransferase is present in the endosperm of any plant." (Decision 32.)
2. In this context, the Board Decision further stated that "Appellant has failed to provide evidence that one of ordinary skill in the art was aware that Met1 is present in the endosperm of any plant type." (Decision 46.)

PRINCIPLES OF LAW

In a decision we consider only those arguments actually made by Appellant. Arguments that Appellant could have made but chose not to make in the Briefs are not considered and are deemed to be waived. *See 37 C.F.R. § 41.37(c)(1)(vii).*

This board serves as a board of review, not a de novo examination tribunal. *See 35 U.S.C. 6(b)* (“The [board] shall, on written appeal of an applicant, review adverse decisions of examiners upon applications for patents.”).

The burden is on the Examiner to set forth a *prima facie* case of obviousness. *See In re Alton*, 76 F.3d 1168, 1175, (Fed. Cir. 1996).

Findings of fact and the conclusions of law must be made in accordance with the Administrative procedure Act, 5 U.S.C. 706 (A), (E) (1994). *See Dickinson v. Zurko*, 527 U.S. 150, 158, 119 S.Ct. 1816, 1821, (1999).

Findings of fact are made by the Examiner during patent Examination.

Whether a ground of rejection is “new” depends on whether the applicant had a “fair opportunity to react to the thrust of the rejection.” *See In re Kronig*, 539 F.2d 1300, 1302-03 (CCPA 1976).

“The Board cannot be said to have presented a new ground of rejection simply by elaborating on the examiner’s rejection or by using different words. *See In re Oetiker*, 977 F.2d 1443, 1445-46 (Fed.Cir.1992).” *Hyatt v. Doll*, No. 2007-1066, slip op. at 27 (Fed. Cir. Aug. 11, 2009).

“A party cannot wait until after the Board has rendered an adverse decision and then present new arguments in a request for reconsideration.”

See In re Cooper v. Goldfarb, 154 F.3d 1321, 1331, (Fed. Cir. 1998).

Under § 41.52, “[a]rguments not raised in the briefs before the Board and evidence not previously relied upon in the brief and any reply brief(s) are not permitted in the request for rehearing.” Because Appellant has not pointed out why the new arguments fall into the exceptions in 37 C.F.R. § 41.52(a)(2) and (a)(3), we decline to consider them.

Unlike the majority, we do not find it in accordance with the Board’s mandate, procedure or existing law or rule to entertain new argument of Appellant in the Request for Rehearing for the reasons herein.

1. Regarding the Written Description rejection, Appellant alleges that the Board raised a new ground of rejection when it said Met1 not shown in endosperm of any plant. (Reh’g 2.)

ANALYSIS

Appellant has not provided evidence that the Board presented a new ground of rejection in the Written Description portion of the Decision. Appellant has inaccurately presented the position of the Board and characterized it as a new ground of rejection.

The Board did not say that Met1 is not shown in the endosperm of any plant as alleged by Appellant. (Reh’g 2.) What the Board said was that the Declaration of “Dr. Jacobson does not … evidence that methyltransferase is present in the endosperm of any plant.” (Decision 32.) In this context, the

Board Decision further stated that “Appellant has failed to provide evidence that one of ordinary skill in the art was aware that MetI is present in the endosperm of any plant type.” (Decision 46.)

Appellant, in the Request for Rehearing, still fails to indicate where in the evidence of record before the Board at the time of the Decision, i.e., in the Declaration of Dr. Jacobson or in the Brief, or Reply Brief, that it is argued or that it is indicated that methyltransferase is present in the endosperm of any plant to support the written description rejection.

Appellant had a full and fair opportunity to present such evidence in response to the Examiner’s finding of lack of possession of the invention and lack of an adequate written description to support the breadth of the claims, (Ans. 6), or even in conjunction with the lack of enablement rejection.

Any argument that Appellant wanted to present should have been presented in the Brief, Reply Brief or Declaration of Dr. Jacobsen. Arguments not so presented are waived. Under § 41.52, “[a]rguments not raised in the briefs before the Board and evidence not previously relied upon in the brief and any reply brief(s) are not permitted in the request for rehearing.” Because Appellant has not pointed out why the new arguments fall into the exceptions in 37 C.F.R. § 41.52(a)(2) and (a)(3), we decline to consider them.

Even more particularly, the written description rejection was raised by the Examiner in the Final Rejection, 8, Answer, 5, and responded to in the Decision on pages 42-47, and therefore does not constitute a new ground of rejection. Furthermore, the thrust of the Examiner’s rejection as addressed

in the Final Rejection at page 5, was “Applicants have not disclosed a single partial sequence that can be used to down-regulate one or more methylating enzymes present in *a plant and produce plants whose seeds have a modified endosperm.*” [Emphasis added.] On page 6 of the Final Rejection, the Examiner argues that “Applicant has not disclosed a representative number of partial Met1 sequences, *or even full length sequences* that can be used to down regulate one or more methylating enzymes and produce a *plant whose seeds have a modified endosperm.*” [Emphasis added.] This argument is also repeated on page 7 of the Final Rejection. With respect to the enablement rejection, the Examiner argues in the Final Rejection, page 8, that “The Office contends that the claims are not just drawn to decreasing the degree of overall DNA methylation, but rather the claims are drawn to decreasing DNA methylation *for the production of modified endosperm.*” The Examiner found that the Specification “does not reasonably provide enablement for claims broadly drawn to a *method of modifying the endosperm from any plant...*” [Emphasis added.] (Final Rej. 8, Answer 7, Dec. 13, 26.) The Examiner indicates in the Answer at page 19 that “Appellant has not described essential regions of the Met1 sequence that can be used *to down regulate a methyltransferase in a plant so that the plant produces seeds with the expected phenotype.*” [Emphasis added.]

Therefore the thrust of the Examiner’s rejection clearly indicated that the Examiner did not believe the evidence of record supported modifying the endosperm of any plant with either full or partial sequences of Met1 to obtain a modified endosperm phenotype. Thus the Board cannot be said to have altered the thrust of the Examiner’s original rejection when it

concluded that Appellant does not reasonably provide enablement and written description for claims broadly drawn to a method of modifying the endosperm from any plant which is argued repeatedly and consistently stated throughout the Final Rejection, Answer and Decision. “The Board cannot be said to have presented a new ground of rejection simply by elaborating on the examiner’s rejection or by using different words. *See In re Oetiker*, 977 F.2d 1443, 1445-46 (Fed.Cir.1992).” *Hyatt v. Doll*, 576 F.3d 1246, 1276 (Fed. Cir. Aug. 11, 2009).

We respectfully note that the Reply Brief does not argue that using a promoter targeting expression of *Arabidopsis* Met 1 to female germ line cells predictably produces the expected phenotype in any plant, including plants other than *Brassica* or *Arabidopsis*. The Appellants had a full and fair opportunity to raise this argument in the Reply Brief, in response to the Examiner’s argument in the Answer.

Appellant presented no argument or evidence in the Brief in response to the argument of the Examiner that the Specification does not reasonably provide enablement for claims broadly drawn to a method of modifying the endosperm from any plant using full or partial sequences of *Arabidopsis* Met1. Moreover, it was Appellant who changed the thrust of the Examiner’s rejection by ignoring the broader issue raised by the Examiner’s rejection, that Appellant has not described essential regions of the Met1 sequence that can be used to down regulate a methyltransferase in a plant so that the plant produces seeds with the expected phenotype, and by only focusing on the written description and enablement of partial sequences of Met1 in the Brief and Reply Brief. The Answer, then, as required, responded to and answered

arguments made in the Brief regarding partial sequences. Any argument Appellant could have made in the Brief to rebut the argument of the Examiner that the Specification does not reasonably provide enablement for claims broadly drawn to a method of modifying the endosperm from any plant, was waived. Appellant had a full and fair opportunity to make this argument in response to the Final Rejection and the Answer, and did not. Appellant may not now introduce new argument or evidence in the Request for Rehearing.

In our decision we essentially agreed with the arguments put forth by the Examiner in the Answer at pages 4-6, that given the disclosure of a single species of *Arabidopsis* Metl sequence, shown only to be capable of modifying endosperm production in one plant species, that the disclosure as filed does not adequately demonstrate possession of the claimed genus encompassing all partial sequences that act to modify the endosperm of any plant, and therefore our analysis does not constitute a new ground of rejection.

We more particularly found that the facts presented with respect to the enablement rejection further supported that the state of the art is unpredictable regarding the ability to down regulate (hypomethylate) MET1 in any plant. We found that the evidence of record showed downregulation of methylating genes produces unpredictable results, producing hypermethylation in some regions of the plant and hypomethylation in others. (Decision FF16.) We found that reduction of sense suppression of an endogenous corresponding gene in a plant produces unpredictable results with evidence that suppression of chalcone synthase genes (CHS) having

70% identity did not result in suppression of petunia CHS. (Decision FF20, FF48.) We found based on the evidence of record that antisense molecules that exhibit less than 100% sequence identity to the target sequence produce unpredictable results. (Decision FF21.) We found, as did the Examiner (Ans. 4) that the evidence showed that there are multiple classes of methyltransferases which differ in target specificity further supporting unpredictability in the art. (Decision FF22.) We further found that the Declaration of Jacobsen was unpersuasive to rebut the Examiner's finding of lack of written description.

Furthermore, the new argument of Appellants regarding the presence of methyltransferase 1 in endosperm of plants fails to address the Examiner's evidence of unpredictability in the art associated with sense suppression of an endogenous corresponding gene in a plant, i.e. Guttersen et al, also within the scope of the pending claims.

Again, in a Decision we consider only those arguments actually made by Appellant. Arguments that Appellant could have made but chose not to make in the Briefs have not been considered and are deemed to be waived. *See* 37 C.F.R. § 41.37(c)(1)(vii).

Finally, this Board sits as a Board of review, not an examining body. If Appellant, after the fact, has determined that additional evidence may be helpful to the Examiner to better understand the nature of the invention or which is evidence in rebuttal to rejections of record, the appropriate procedural recourse is continued prosecution of the application and presentation of such evidence before the Examiner, not this Board. The new

arguments of Appellant may require additional search on the part of the Examiner and are not properly before this Board.³

For the reason herein, We would decline to entertain Appellant's new argument or alter our original finding that, with respect to the written description rejection that in this unpredictable field of science that additional exemplification in the Specification is required to describe modification of endosperm in any plant, as claimed.

CONCLUSION OF LAW

Appellant has not shown that the Board presented a new ground of rejection in the Decision or changed the thrust of the Examiner's rejection. Appellant cannot present new evidence in a Request for Rehearing.

2. Appellant alleges that the Board misapprehended nature of invention.

The Board clearly understood that Appellant proposes the use of an antisense sequence targeted by promoter to female endosperm, or the use of

³ Possible additional relevant art, for example, includes U.S. 6,011,200 filed July 31, 1996 to Dellaporta et al., (WO 9804725), which discloses reducing the amount of methylated DNA present in a plant and plant seeds (Col. 5, ll. 14-34; col. 2, ll. 20) including *Arabidopsis* Met1 (Col. 5, ll. 28-29 and col. 12, ll. 48-50). Ap3 and seed specific promoters may be used (Col. 7, ll. 60-62.) The use of antisense technology to downregulate methylase is further taught. (Col. 8, ll. 62.) This patent further discloses that only certain monocots can be transformed using agrobacterium. (Col. 10, ll. 64-66.) Seed is known to comprise endosperm. Thus downregulating a MET1 using a seed specific promoter would inherently result in a modified endosperm.

full or partial copies of Met1 genes targeted by promoter to female endosperm present in the plant, leading to hypomethylation of Met 1 and thus larger endosperm in any plant. (Spec. 18.)

We see no further issue here.

3. Appellant alleges that the Board overlooked arguments supporting the written description of claims 63, 69, 76, 86-93.

Appellant attempts to argue claims 63, 69, 76, and 86-93 separately by simply listing their limitations (App. Br. 25-27). Technically, this does not constitute a separate argument under 37 C.F.R. 41.37(c)(1)(vii) ("A statement which merely points out what a claim recites will not be considered an argument for separate patentability of the claim."). Moreover, Appellant failed to specifically point out the error in the Examiner's rejection with respect to these claims.

We see no further issue here.

Written Description Example 12

4. Appellant alleges that the Board overlooked the written description guidelines.

Appellant argues that Written Description Guidelines, Example 12 supports written description of the present claims. (Reh.'g 4.)

Because the written description guidelines were revised after the Briefings in this case, we entertain the Appellant's arguments regarding Written Description Guidelines, Example 12.

FINDINGS OF FACT

3. Example 12 of the Written Description Guidelines has a caveat that different outcomes may result due to the subject matter being claimed and the knowledge in the art. Written Description Guidelines, Revision 1 (March 25, 2008), Example 12, practice note.

4. The differences between monocots and dicots are also acknowledged in the Specification, particularly where the Specification acknowledges that dicot plants produce exalbuminous seeds, -- that is, mature seeds lack an endosperm. (Spec. 1-2.)

5. Most monocots produce endosperm that represents a significant portion of the seed. (Spec. 1.)

6. The Specification merely speculates that “increasing the size of the endosperm or its ability to accumulate storage products is likely to increase individual seed weight.”[Emphasis added.] (Spec. 1.)

7. Further according to the Specification, it is admitted that the “genetic basis for the resistance to increased seed weight encountered in conventional breeding programs is not understood.” (Spec. 2.)

8. Even more particularly, Specification, Example 4, (Spec. 32-33) acknowledges that, at the time of filing of the application, the introduction of female and male germ-line specific demethylating genes into transgenic plants and then subjecting them to crosses, resulted in variable outcomes that depended upon the particular transgenic plant. [Emphasis added.] (Spec. 32.)

9. Page 230 of Finnegan 2000 indicates that other proteins other than methyltransferases may be required for DNA methylation. Because other

plant proteins may effect or counter endosperm methylation, and such proteins may differ from one plant to another, such a fact further supports unpredictability in the relevant art.

ANALYSIS

Example 12 of the Written Description Guidelines has a caveat that different outcomes may result due to the subject matter being claimed and the knowledge in the art. Written Description Guidelines, Revision 1 (March 25, 2008), Example 12, practice note.

While we acknowledge in Written Description Example 12 that one of ordinary skill in the art would have been in possession of a genus of antisense oligonucleotides based on the single species of Met 1, we do not agree that one of ordinary skill in the art would have been in possession of the subject matter of claim 20.

As recognized by the Examiner throughout the Final Rejection (Final Rej. 8), the claim requires more than an antisense sequence to Met 1. Claim 20 requires that an antisense sequence to Met 1 provide a result not only of down regulating Met1 but also of producing a phenotype resulting in a modified endosperm in any plant, including both monocots and dicots.

The divergent genetic differences between monocots and dicots, and the inherent difficulties in transforming them are punctuated in the patent case law. *In re Goodman*, 11 F.3d 1046 (Fed. Cir. 1993); *Mycogen Plant Science Inc. v. Monsanto Co.*, 243 F.3d 1316 (Fed. Cir. 2001); *In re Plant Genetic Systems N.V. v. DeKalb Genetics Corp.*, 315 F.3d 1335 (Fed. Cir. 2003); *In re Monsanto Co. v. Syngenta Seeds Inc.*, 503 F.3d 1352 (Fed. Cir.

2007). In fact, the ability to transform monocots such as producing transgenic corn, was not acknowledged until 1992-1993. *In re Monsanto Co. v. Syngenta Seeds Inc.*, 503 F.3d 1352 (Fed. Cir. 2007). The differences between monocots and dicots are also acknowledged in the Specification, particularly where the Specification acknowledges that dicot plants produce exalbinous seeds, -- that is, mature seeds lack an endosperm. (Spec. 1-2.)

Most monocots produce endosperm that represents a significant portion of the seed. (Spec. 1.) The Specification merely speculates that “increasing the size of the endosperm or its ability to accumulate storage products is likely to increase individual seed weight.”[Emphasis added.] (Spec. 1.) Further according to the Specification, the “genetic basis for the resistance to increased seed weight encountered in conventional breeding programs is not understood.” (Spec. 2.) Even more particularly, Specification, Example 4, (Spec. 32-33) acknowledges that the introduction of female and male germ-line specific demethylating genes into transgenic plants and then subjecting them to crosses, resulted in variable outcomes that depended upon the particular transgenic plant. [Emphasis added.] (Spec. 32.) The Examiner’s concern relating to whether the claimed method would work in both monocots and dicots is evidenced by the Final Rejection, page 11.⁴

⁴ At least one publication indicates that monocots and dicots have evolved “distinct mechanisms for interpretation of methylation patterns.” Springer et al., *Evolutionary Divergence of Monocot and Dicot Methyl-CpG-binding domain Proteins*, 38 PLANT PHYSIOLOGY, 92-104 (May 2005.)

Even if we were to consider Appellant's new argument (Reh'g 2) concerning the ubiquitous nature of methyltransferases in plant reproductive tissues, we would have to weigh this fact in view of other new facts of record supporting unpredictability of the claimed method of producing a modified endosperm targeting expression to female germ line cells by reducing methylation, including the fact, also on page 230 of Finnegan 2000 (pointed to by Appellant to support that methyltransferases are ubiquitous in plant reproductive tissues) which indicates that other proteins and factors other than methyltransferases may be required for DNA methylation, further supporting unpredictability in the art.

We, as did the Examiner, acknowledge that Appellant has enabled and shown that down regulating the Met 1 gene in the dicot *Arabidopsis* or *Brassica* creates seeds with a modified endosperm. (Decision 42.) However, we find a significant difference in claim scope and subject matter claimed between Written Description Example 12 and broad claim 20, and therefore we conclude that a different outcome results due to the breadth of the subject matter being claimed and the state of the knowledge in the art.⁵ Thus, we do not find that Written Description Example 12 requires a different outcome.

We note that the majority position in the Decision on Rehearing relies on the minority position taken in the dissent in *Lizardtech*, i.e., that the

⁵ For further discussion of the relevance of Federal Circuit decisions related to written description rejections in cases in which the claims are broader than the disclosed embodiments see *Lizardtech Inc. v. Earth Resource Mapping Inc.*, 433 F.3d 1373 (Fed. Cir. 2006), particularly the Rader, Gajarsa dissent.

written description doctrine is or should be limited to whether the written description shows possession of the claimed invention. This position is the minority position, is contrary to the precedential majority position in *Lizardtech*, indicating that claims should not be broader than the disclosed embodiments under the written description doctrine. The minority position is dicta, and does not have the force of law.

Falkner v. Inglis

Appellant alleges that Board overlooked the binding case law of *Falkner v. Inglis*, 448 F.3d 1357 (Fed. Cir. 2006). (Reh'g 6.)

Appellant alleges that *Falkner v. Inglis* states that Examples are not required and only enough must be conclude to convince a person of skill in the art that the inventor posses the invention. Appellant alleges that the Board has not given due regard to the subject matter involved. (Reh'g 7.)

We find that due to the subject matter claimed and the state and the knowledge in the art that *Falkner v. Inglis* is not controlling. In particular, due to the well known differences between monocots and dicots, and due to the paucity of evidence and examples provided in the Specification with respect to other plant types within the scope of the claims, in this unpredictable art, we do not find that *Falkner v. Inglis* is controlling.

Falkner v. Inglis essentially found that examples are not necessary to support adequacy of written description, provided the patent specification otherwise provides sufficient information to convince person of ordinary skill in art that inventor possessed claimed invention. In particular *Falkner* quotes Capon in this regard, reaffirming that:

The descriptive text needed to meet these requirements varies with the nature and scope of the invention at issue, and with the scientific and technologic knowledge already in existence. The law must be applied to each invention that enters the patent process, for each patented advance is novel in relation to the state of the science. Since the law is applied to each invention in view of the state of relevant knowledge, its application will vary with differences in the state of knowledge in the field and differences in the predictability of the science.

In re Falkner v Inglis, 448 F.3d 1357, 1368 (Fed. Cir. 2006).

In our Decision, page 45, we indicated that Appellant's arguments did not persuade us and that we relied on *Capon v. Eshhar*, 418 F.3d 1349, 1357 (Fed. Cir. 2005) and found it controlling of the facts in this case. It is the unpredictability of the subject matter involved as supported by the evidence of record that is not addressed by *Falkner v. Inglis*. Since the written description law is applied to each invention in view of the state of relevant knowledge, its application will vary with differences in the state of knowledge in the field and differences in the predictability of the science. See also Written Description Guidelines, Example 12, caveat. It is well recognized that in the "unpredictable" fields of science, it is appropriate to recognize the variability in the science in determining the scope of the coverage to which the inventor is entitled. Such a decision usually focuses on the exemplification in the Specification. See, e.g., *Enzo Biochem, Inc. v. Gen-Probe Inc.*, 323 F.3d 956 (Fed. Cir. 2002).

Thus, we find that *Capon v. Eshhar* dictates a finding of lack of written description in this case.

4. Appellant request a point of clarification regarding claims 83, 84, 91 and 92.

We regret the error on page 47 stating that the written description rejection did not apply to claims 83, 84, 91 and 91. As indicated in the Summary of the Decision, the enablement rejection of claims 83, 84, 91 and 92 was reversed. All other written description rejections and enablement rejections are affirmed.

5. Appellant alleges that the Board raised a new ground of rejection with respect to predictability concerning the enablement rejection. (Reh'g 9.)

The Examiner raised the issue of unpredictability in the art with respect to the Enablement rejection in the Answer at pages 10, 21, 31. In our decision page 27, 32 we addressed the issue of unpredictability with respect to the enablement issue. Thus, we did not raise a new ground of rejection based on predictability with respect to the enablement issue.

“The Board cannot be said to have presented a new ground of rejection simply by elaborating on the examiner's rejection or by using different words. *See In re Oetiker*, 977 F.2d 1443, 1445-46 (Fed.Cir.1992).”
Hyatt v. Doll, No. 2007-1066, slip op. at 27 (Fed. Cir. Aug. 11, 2009).

“A party cannot wait until after the Board has rendered an adverse decision and then present new arguments in a request for reconsideration.”
Cooper v. Goldfarb, 154 F.3d 1321, 1331 (Fed. Cir. 1998). Under § 41.52, “[a]rguments not raised in the briefs before the Board and evidence not previously relied upon in the brief and any reply brief(s) are not permitted in

the request for rehearing.” Because Appellant has not pointed out why the new arguments fall into the exceptions in 37 C.F.R. § 41.52(a)(2) and (a)(3), we decline to consider them.

6. Appellant alleges that the Board overlooked arguments supporting the sufficiency of enablement of claims 63, 69, 76 and 86-93, Rehearing 10.

We indicated in the Decision, page 41, that Appellant attempts to argue claims 63, 69, 76, and 86-93 separately by simply listing their limitations (App. Br. 45-47) were insufficient. Technically, this does not constitute a separate argument under 37 C.F.R. 41.37(c)(1)(vii) (“A statement which merely points out what a claim recites will not be considered an argument for separate patentability of the claim.”). Moreover, Appellant failed to specifically point out the error in the Examiner’s rejection with respect to these claims.

In sum, with respect to enablement, Appellant admits in the Specification that the introduction of female and male germ-line specific demethylating genes into transgenic plants and then subjecting them to crosses, resulted in variable outcomes that *depended upon the particular transgenic plant* (FF8), thus Appellant essentially admits he has not enabled or described plants other than those exemplified in the Specification, *Brassica* and *Arabidopsis*.

With respect to the written description rejection, the majority position in the Decision on Rehearing relies on the minority position taken in the dissent in *Lizardtech*, i.e., that the written description doctrine is or should

be limited to whether the written description shows possession of the claimed invention. This position is the minority position, and is contrary to the precedential majority position in *Lizardtech*, indicating that claims should not be broader than the disclosed embodiments under the written description doctrine. The minority position in *Lizardtech* is dicta, and does not have the force of law. Nor does written description guideline Example 12 enjoy the force of law, to support the majority's position. Thus the majority position taken here is not supported by legal precedent.

The evidence of record supports denial of the Request for Rehearing.

lp

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